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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/286,818	04/06/1999	RONALD L. REAM	P99.0082	5472

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[REDACTED] EXAMINER

TRAN, SUSAN T

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1615

DATE MAILED: 04/07/2003

36

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/286,818	REAM ET AL.	
	Examiner	Art Unit	
	Susan Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 30 January 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-12 and 19-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-12, 19-22 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

4) Interview Summary (PTO-413) Paper No(s) _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment filed 01/30/03.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, and 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 19 are indefinite in the use of the phrase "typical amount". What is typical amount? The examiner has not been able to determine what can be considered a typical amount? Thus, the metes and bounds of the patent protection desired are unascertainable. Further clarification is suggested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-11, and 19, 20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cherukuri et al. US 5,013,716.

Cherukuri teaches chewing gum composition comprising elastomer as gum base, fats, oils, softener, filler, wax, colorant, plasticizer, acidulant, bulking agent, and sweetener (columns 8-10). The composition further comprises medicament (column 6). Cherukuri does not teach chewing the chewing gum, and continuing to chew the chewing gum to create a fluid pressure or saliva content of medicament of approximately 1700 to about 4400 ppm, causing the medicament to absorb through oral mucosa. However, chewing a chewing gum is obvious to one of ordinary skill in the art, and by continuously chewing the chewing gum, it would have been obvious to one of ordinary skill in this art that the medicament release into the saliva is either swallowed or absorbed through the oral mucosa. Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to chew or continue chewing the chewing gum to obtain the desirable amount of medicament to achieve a desired effect.

Claims 5, 12, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cherukuri et al.

Cherukuri is relied upon for the reason stated above. Cherukuri does not teach chewing the chewing gum at least twice a day. However, it is the position of the examiner that the amounts of medicament being administered are within the capability of the skilled artisan to determine a suitable dosage according to the daily needed basis.

Claims 1, 7, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cherukuri et al., and Hausler et al. US 5,922,347.

Cherukuri is relied upon for the reason stated above. Cherukuri does not teach chewing the chewing gum, and continuing to chew the chewing gum to force the medicament to absorb through oral mucosa

Hausler teaches a stable chewing gum formulation comprises active drug (column 2, lines 8-56), filling, emulsifying, waxes, plasticising, and sugar (column 3, lines 11-67). Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to modify Cherukuri's chewing gum composition with the teaching of Hausler to obtain a safe and stable chewing gum containing medicament, which is tolerated by the mucous membrane, because the references teach the advantageous results of medicament chewing gum compositions useful in pharmaceutical art.

Response to Arguments

Applicant's arguments filed 01/30/03 have been fully considered but they are not persuasive.

Applicant argues that Cherukuri teaches the amount of medicament used in general is "the ordinary dosage required to obtain the desired result", and therefore, Cherukuri is clearly teaching away from the present invention where less than the ordinary amount is used. In response to applicant's argument, since applicant has not defined the "typical amount", the examiner cannot establish the patentability distinct between "less than a typical amount" and "ordinary amount" disclosed by Cherukuri.

Applicant argues that Cherukuri does not disclose or remotely suggest a method of delivering a medicament which includes the step of chewing gum for at least two

minutes. However, absent of showing evidence on the contrary, it would have been obvious for one of ordinary skill in this art to chew Cherukuri's chewing gum in order to obtain a desired effect of the medicament in the chewing gum.

Applicant argues that Cherukuri is completely silent as to any methods of chewing the chewing gum for at least two minutes to deliver a medicament. Although Cherukuri is silent as to the time of chewing the chewing gum, it is the position of the examiner that it would have been obvious for one of ordinary skill to continue chewing the chewing gum for at least 2 minutes, because Cherukuri teaches a chewing gum composition comprising medicament useful in pharmaceutical art. Therefore, it would have been obvious to the skilled artisan to keep chewing until the desired effect is obtained.

Applicant argues that Hausler does not teach any methods for delivering a medicament in a chewing gum composition that involves using less than the typical amount of agent that is swallowed by an individual, and therefore, Hausler does not remedy the deficiencies of Cherukuri. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Again, the examiner has not been able to compare "less than a typical amount" and "ordinary amount" taught by Cherukuri and Hausler. Thus, it is the position of the

examiner that no patentability distinct can be seen in the particular limitation, because "less than a typical amount" can be any ordinary amount.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600